

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

DDM

Display Date 7-27-04

Publication Date 7-28-04

Certifier R. LEDESMA

[Docket No. 1987C-0023]

Listing of Color Additives Subject to Certification; D&C Black No. 2

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of D&C Black No. 2 (a high-purity furnace black, subject to FDA batch certification) as a color additive in the following cosmetics: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel. This action is in response to a petition filed by the Cosmetic, Toiletry, and Fragrance Association.

DATES: This rule is effective [*insert date 30 days plus 1 business day after date of publication in the Federal Register*]. Submit objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*]. See section VIII of this document for information on the filing of objections.

ADDRESSES: Submit written objections and requests for a hearing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

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FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3423.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of March 13, 1987 (52 FR 7933), FDA announced that a color additive petition (CAP 7C0208) had been filed by the Cosmetic, Toiletry, and Fragrance Association, Inc., 1110 Vermont Ave. NW., Washington, DC 20005 (current address, 1101 17th St. NW., suite 300, Washington, DC 20036-4702). The petition proposed to amend the color additive regulations in part 74 (21 CFR part 74, subpart C) to provide for the safe use of carbon black as a color additive for coloring cosmetics generally, including cosmetics for use in the area of the eye. The petitioner has now limited its proposed use of carbon black to the following cosmetics: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel. During its review of the petition, the agency determined that the subject carbon black is a fine-particle high-purity furnace black that will require batch certification by FDA. The agency intends to give each certified batch of the subject color additive the name D&C Black No. 2. Therefore, this color additive will be identified as D&C Black No. 2.

The petitioner has requested the use of D&C Black No. 2 in cosmetics, including cosmetics for use in the area of the eye. The term “area of the eye” is defined in § 70.3(s) (21 CFR 70.3(s)) as “the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and

conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.”

The regulation in 21 CFR 70.5(a) states that “No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in the area of the eye unless such listing or certification of such color additive specifically provides for such use.”

II. Identity and Specifications

D&C Black No. 2 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by injecting a heated aromatic petroleum oil feedstock into the combustion zone of a natural gas fired furnace. The reaction is quenched with water and the carbon particles are further cooled and collected on a fabric filter. The high-purity furnace black that is the subject color additive of this rule consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 200 to 260 meters²/gram.

As explained under III.B of this document, the color additive D&C Black No. 2 may contain low levels of potentially carcinogenic polynuclear aromatic hydrocarbon (PAH) contaminants. To limit the amounts of these contaminants in the color additive, FDA is requiring that D&C Black No. 2 for use in cosmetics be from a batch of the color additive certified by FDA, and is setting specifications for total PAHs, benzo[*a*]pyrene (B[*a*]P), and dibenz[*a,h*]anthracene. Because any PAH contaminants in the color additive can tightly bind to the carbon particles, the bioavailability of PAHs will be inversely related to the surface area of the carbon particles. Therefore, the agency is setting a specification for surface area, determined by the nitrogen Brunauer, Emmett, Teller (BET) method.

In general, the surface area of the carbon particles is also inversely related to their particle size. Because eye irritation may be caused by larger carbon particles, a specification for surface area by nitrogen BET will also limit the size of the carbon particles to those fine enough to ensure eye area safety.

To limit the amounts of heavy metals in the color additive, which substances may be derived from the manufacturing process water and the feedstock, the agency is also setting specifications for arsenic, lead, and mercury.

For a certifiable color additive, the sum of total color plus the levels of appropriate impurities should approximate 100 percent, allowing mass accountability. The total color from D&C Black No. 2 comes from the elemental carbon itself. The levels of appropriate impurities can be obtained from data for ash, volatile matter, and total sulfur. Therefore, the agency is setting specifications for total color (as carbon), ash content, weight loss on heating, and total sulfur.

III. Safety Evaluation

A. Determination of Safety

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(b)(4)), the so-called “general safety standard” for color additives, a color additive cannot be listed for a particular use unless a fair evaluation of the data and information available to FDA establishes that the color additive is safe for that use. FDA’s color additive regulations (§ 70.3(i)) define safe as “convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.”

The anticancer or Delaney clause of the color additive amendments (section 721(b)(5)(B) of the act) provides that for any use of a color additive

which will or may result in ingestion of all or part of such additive, the color additive shall be deemed to be unsafe and shall not be listed if the additive is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal (section 721(b)(5)(B)(i) of the act). Further, under section 721(b)(5)(B)(ii) of the act, for any use of a color additive which will not result in ingestion of any part of such additive, the color additive shall be deemed to be unsafe and shall not be listed if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found to induce cancer in man or animal.

Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984)).

B. Safety of Petitioned Use of the Additive

D&C Black No. 2 is inert. Its insolubility and lack of toxicity, coupled with a history of safe use of activated carbon in medicine, contribute to the agency's conclusion that the color additive itself is safe for its proposed uses. However, the color additive has been shown to contain low levels of PAH impurities, some of which are carcinogenic. To minimize exposure to contaminants, the agency is setting limits for the following PAHs as a proportion of D&C Black

No. 2: total PAHs (0.5 milligram (mg)/kilogram (kg)); B[a]P (0.005 mg/kg); and dibenz[*a,h*]anthracene (0.005 mg/kg).

Current data have shown B[a]P to be one of the most potent carcinogens of the PAH family. To assess the risk from exposure to PAHs, FDA has used toxic equivalency factors to express the comparative toxicity of PAHs as fractions of the toxicity of B[a]P. This approach expresses the amount of PAHs present in terms of B[a]P equivalents and estimates the risk for a mixture of PAHs as if it were one chemical compound. Under this system, B[a]P has been assigned a B[a]P toxic equivalency of 1. FDA has estimated the exposure to B[a]P equivalents from the use of high-purity furnace black in cosmetics to be no greater than 7.2×10^{-10} mg/kg body weight/day (Ref. 1). In estimating the exposure to B[a]P equivalents from the petitioned use of the color additive, FDA assumed that both B[a]P and dibenz[*a,h*]anthracene were present at their proposed limits of 0.005 mg/kg and that each of the other possible PAH contaminants would be present in equal amounts, with a total PAH concentration of 0.5 mg/kg (Ref. 1). Based on the evidence presented in the petition, the agency also concluded that no more than 10 percent of the total PAHs present were likely to be extractable from the additive under typical use conditions, and thus available for absorption by the body (Refs. 2 and 3).

The agency used data from a carcinogenesis bioassay on B[a]P, conducted by H. Brune, et al., to estimate the upper-bound limit of lifetime human risk from exposure to B[a]P equivalents resulting from the petitioned use of the color additive (Ref. 4). The authors reported treatment-related benign forestomach tumors or esophageal tumors in male rats exposed to B[a]P. Using a linear-at-low-dose extrapolation method and tumor incidence data from the H. Brune, et al. study, the FDA estimated the carcinogenic unit risk for B[a]P

to be $1.75 \text{ (mg/kg body weight/day)}^{-1}$. Using this carcinogenic risk for B[a]P and an estimated daily exposure of 7.2×10^{-10} mg of B[a]P equivalents/kg body weight/day, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the additive is 1.3×10^{-9} , or less than 1 in 1 billion (Refs. 1 and 5 through 7).

Because conservative assumptions were used to estimate exposure, and PAHs bind tightly to carbon black and are not expected to be bioavailable, the average individual exposure to B[a]P toxic equivalents is expected to be substantially less than the estimated exposure (Refs. 5 and 6). The actual risk will likely be less than the calculated upper-bound limit of risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to PAHs would result from the petitioned use of the additive.¹

In addition, no toxicity was noted in studies provided by the petitioner to support the safety of D&C Black No. 2 to color cosmetics intended for use in the area of the eye (Ref. 8).

IV. Conclusions

Based on the data in the petition and other relevant considerations discussed in section III of this document, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of D&C Black No. 2 as a color additive in the following cosmetics: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel. The agency also concludes that the color additive will achieve its intended technical effect, and thus, is suitable for this use. The agency further concludes that in accordance with 21 CFR 71.20(b), batch

¹ FDA has also estimated the upper-bound limit of lifetime human risk to PAHs using the worst-case assumption that all PAHs in the additive have the same carcinogenic potency as B[a]P. Based on this highly conservative approach, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the additive is 1.5×10^{-8} , or about 1 in 100 million (Ref. 6).

certification of D&C Black No. 2 is necessary to protect the public health because of the need to limit the levels of PAHs, some of which have been shown to be carcinogenic. Therefore, part 74 should be amended as set forth in this document.

V. Inspection of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from Jensen, Division of Product Manufacture and Use, to White, Division of Petition Control, March 23, 1998.
2. Memorandum from Cramer, Food and Color Additives Review Section, to Kashtok, Direct Additive Branch, July 25, 1990.
3. Memorandum from Folmer, Division of Petition Review Chemistry Review Group, to Johnston, Division of Petition Review, September 30, 2003.
4. Brune, H., R. P. Deutsch-Wenzel, M. Habs, S. Ivankovis, and D. Schmahl, "Investigation of the Tumorigenic Response to Benzo[a]pyrene in Aqueous Caffeine Solution Applied Orally to Sprague-Dawley Rats," *Journal of Cancer Research and Clinical Oncology*, 102:153–157, 1981.
5. Memorandum from Carlson, Division of Petition Review, to Peiperl, Division of Petition Review, July 2, 2003.
6. Memorandum from Kraeling, Cosmetic Toxicology Branch, to Peiperl, Division of Petition Control, April 22, 2003.
7. Memorandum from Folmer, Division of Petition Review Chemistry Review Group, to Peiperl, Division of Petition Review, July 1, 2003.
8. Memorandum from Kraeling, Office of Cosmetics and Colors, to Peiperl, Division of Petition Review, July 15, 1999.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the

regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

■ 1. The authority citation for 21 CFR part 74 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 74.2052 is added to subpart C to read as follows:

§ 74.2052 D&C Black No. 2.

(a) *Identity.* The color additive D&C Black No. 2 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by the combustion of aromatic petroleum oil feedstock and consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 200 to 260 meters (m)²/gram.

(b) *Specifications.* D&C Black No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Surface area by nitrogen BET (Brunauer, Emmett, Teller) method, 200 to 260 m²/gram.

(2) Weight loss on heating at 950 °C for 7 minutes (predried for 1 hour at 125 °C), not more than 2 percent.

(3) Ash content, not more than 0.15 percent.

(4) Arsenic (total), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million).

(5) Lead (total), not more than 10 mg/kg (10 parts per million).

(6) Mercury (total), not more than 1 mg/kg (1 part per million).

(7) Total sulfur, not more than 0.65 percent.

(8) Total PAHs, not more than 0.5 mg/kg (500 parts per billion).

(9) Benzo[e]pyrene, not more than 0.005 mg/kg (5 parts per billion).

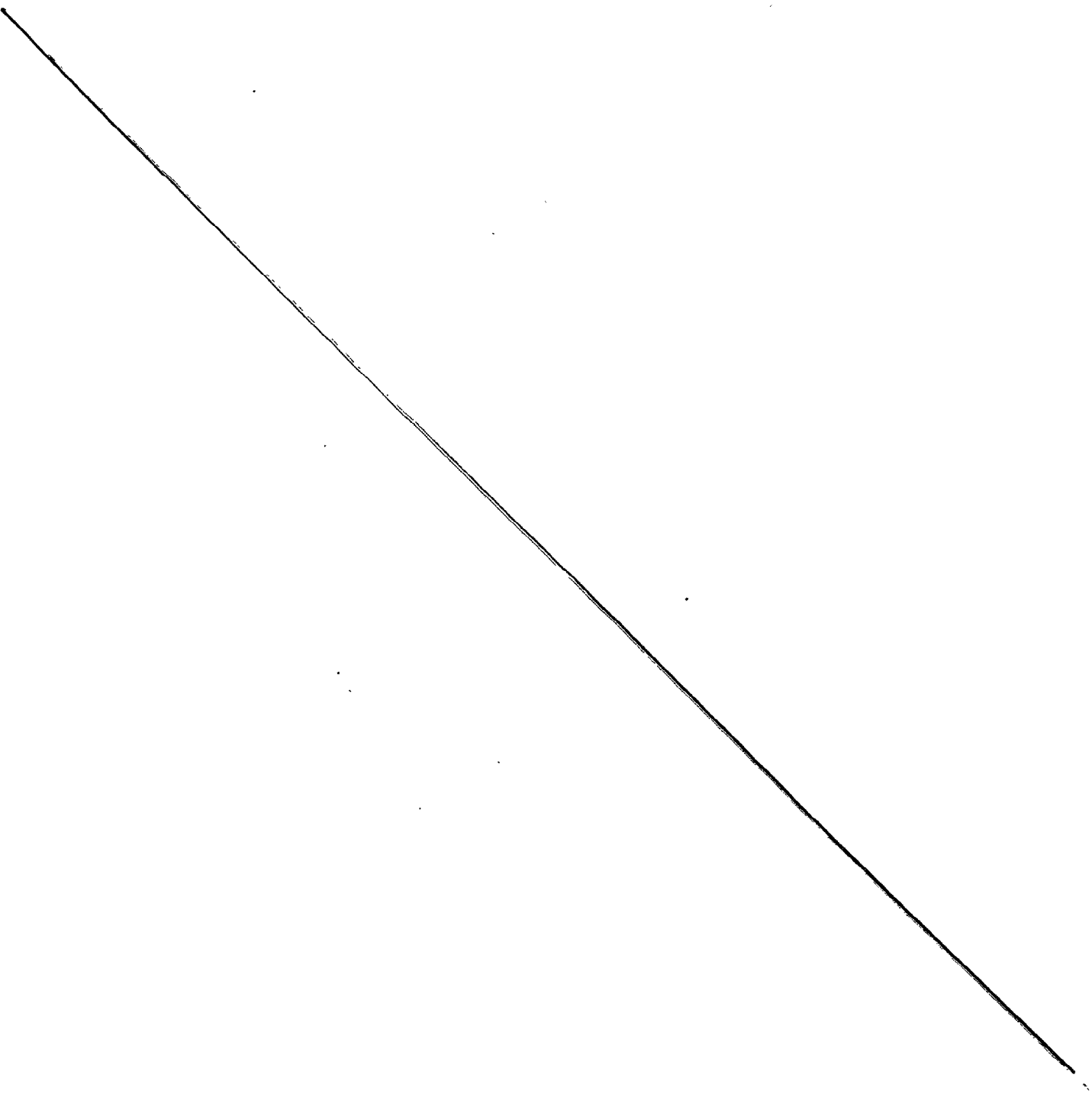
(10) Dibenz[a,h]anthracene, not more than 0.005 mg/kg (5 parts per billion).

(11) Total color (as carbon), not less than 95 percent.

(c) *Uses and restrictions.* D&C Black No. 2 may be safely used for coloring the following cosmetics in amounts consistent with current good

manufacturing practice: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.

(d) *Labeling*. The label of the color additive shall conform to the requirements of § 70.25 of this chapter.



(e) *Certification*. All batches of D&C Black No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

Dated: 7/16/04
July 16, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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